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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,275	02/11/2005	Benjamin Geiger	29140	9948

7590

10/16/2006

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EXAMINER

CARLSON, KAREN C

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/524,275

Applicant(s)

GEIGER, BENJAMIN

Examiner

Karen Cochrane Carlson, Ph.D.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1656

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3 and 7-12, drawn to a polynucleotide encoding a chimeric polypeptide, and the chimeric polypeptide, the chimer comprising a first region that binds to a detectable molecule (fluorogenic moiety) and a second region that binds to a biological component, polypeptide, classified in class 530, subclass 350.
- II. Claims 1, 2 and 7-11, drawn to a polynucleotide encoding a chimeric polypeptide, and the chimeric polypeptide, the chimer comprising a first region that binds to a detectable molecule (chromogenic moiety) and a second region that binds to a biological component, polypeptide, classified in class 530, subclass 350.
- III. Claims 1, 2 and 7-11, drawn to a polynucleotide encoding a chimeric polypeptide, and the chimeric polypeptide, the chimer comprising a first region that binds to a detectable molecule (light emitting moiety) and a second region that binds to a biological component, polypeptide, classified in class 530, subclass 350.
- IV. Claims 1, 2 and 7-11, drawn to a polynucleotide encoding a chimeric polypeptide, and the chimeric polypeptide, the chimer comprising a first region that binds to a detectable molecule (radioactive moiety) and a second region that binds to a biological component, polypeptide, classified in class 530, subclass 350.
- V. Claims 1, 4-6, 7-10, and 13-15, drawn to a polynucleotide encoding a chimeric polypeptide, and the chimeric polypeptide, the chimer comprising a first region that binds to a detectable molecule (antigen binding region of an antibody) and

Art Unit: 1656

a second region that binds to a biological component, polypeptide, classified in class 530, subclass 350.

- VI. Claims 16-22, drawn to a method of highlighting cell compartments in an organism by providing a chimeric polypeptide comprising a first region that binds to a detectable molecule and a second region that binds to a biological component, polypeptide, classified in class 435, subclass 7.1.
- VII. Claims 23-33, drawn to a method of identifying a phenotype abnormality by providing a chimeric polypeptide comprising a first region that binds to a detectable molecule and a second region that binds to a biological component, polypeptide, classified in class 435, subclass 7.1.
- VIII. Claims 32-41, drawn to a method of identifying the presence of an infectious agent in a subject by providing a chimeric polypeptide comprising a first region that binds to a detectable molecule and a second region that binds to a biological component, polypeptide, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Claim 1 is a linking claim that is anticipated by the prior art teachings for His-tagged receptor ligands, for example. Therefore, because the link has been broken, the specific detectable molecules of Inventions I-V are patentably distinct because the polypeptide comprises different binding moieties and they differ in structure and in function.

Inventions I, II, III, IV, or V and Inventions VI, VII, or VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any one of Inventions VI, VII, or VIII.

Art Unit: 1656

The methods of Inventions VI, VII, or VIII are related in that each method requires the use of the product of any one of Inventions I-V. However, the steps and end points of the methods are wholly different and therefore Inventions VI, VII, and VIII are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1656

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946.

The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink that reads "Karen Cochrane Carlson Ph.D." with a stylized flourish at the end.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER